Complete Summary

GUIDELINE TITLE

Colorectal cancer screening.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Colorectal cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Jun. 27 p. [57 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Colorectal cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Jun. 50 p.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Colorectal cancer

GUIDELINE CATEGORY

Evaluation
Prevention
Risk Assessment
Screening

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To increase the number of people aged 50 and older who are up-to-date with colorectal screening
- To increase the number of patients who have had appropriate screening for colorectal cancer using a screening test method discussed and agreed upon by both the patient and his/her physician

TARGET POPULATION

Patients meeting all of the following criteria for routine screening for colorectal cancer:

- 50 years old or, if African American, 45 years old
- No personal history of polyps and/or colorectal cancer
- No personal history of inflammatory bowel disease
- No family history of colorectal cancer in one first-degree relative diagnosed before age 60, or two first-degree relatives diagnosed at any age
- No family history of adenomatous polyps in one first-degree relative diagnosed before age 60

INTERVENTIONS AND PRACTICES CONSIDERED

1. Prescreening education and counseling
2. Risk assessment and determination of need for increased risk surveillance
3. Stool testing (guaiac-based fecal occult blood [gFOBT] test, fecal immunochemical testing [FIT], and stool deoxyribonucleic acid [sDNA] testing)
4. 60 mm flexible sigmoidoscopy with or without stool test
5. Double-contrast barium enema
6. Computed tomographic (CT) colonography
7. Colonoscopy

MAJOR OUTCOMES CONSIDERED

- Incidence of and mortality rates from colorectal cancer
- Cost-effectiveness of screening measures
- Adverse effects of screening measures
- Sensitivity and specificity of screening tests for colorectal cancer

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A literature search of clinical trials, meta-analyses, and systematic reviews is performed.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Each guideline, order set, and protocol is developed by a 6- to 12-member work group that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, along with an Institute for Clinical Systems Improvement (ICSI) staff facilitator. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 members may be recruited from medical groups or hospitals outside of ICSI.

The work group will meet for seven to eight three-hour meetings to develop the guideline. A literature search and review is performed and the work group

members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and footnotes and literature citations.

Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Critical Review Process

Every newly developed guideline or a guideline with significant change is sent to the Institute for Clinical Systems Improvement (ICSI) members for Critical Review. The purpose of critical review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the guideline. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes necessary across systems in their organization to implement the guideline.

All member organizations are expected to respond to critical review guidelines. Critical review of guidelines is a criterion for continued membership within the ICSI.

After the critical review period, the guideline work group reconvenes to review the comments and make changes, as appropriate. The work group prepares a written response to all comments.

Approval

Each guideline, order set, and protocol is approved by the appropriate steering committee. There is one steering committee each for Respiratory, Cardiovascular, Women's Health, and Preventive Services. The Committee for Evidence-based Practice approves guidelines, order sets, and protocols not associated with a particular category. The steering committees review and approve each guideline based on the following:

- Member comments have been addressed reasonably.

- There is consensus among all ICSI member organizations on the content of the document.
- Within the knowledge of the reviewer, the scientific recommendations within the document are current.
- Either a critical review has been carried out, or to the extent of the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that a new round of critical review is not needed.

Once the guideline, order set, or protocol has been approved, it is posted on the ICSI Web site and released to members for use. Guidelines, order sets, and protocols are reviewed regularly and revised, if warranted.

Revision Process of Existing Guidelines

ICSI scientific documents are revised every 12 to 36 months as indicated by changes in clinical practice and literature. Every 6 months, ICSI checks with the work group to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Prior to the work group convening to revise the document, ICSI members are asked to review the document and submit comments. During revision, a literature search of clinical trials, meta-analysis, and systematic reviews is performed and reviewed by the work group. The work group will meet for 1-2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

If there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations, it is sent to members to review prior to going to the appropriate steering committee for approval.

Review and Comment Process

ICSI members are asked to review and submit comments for every guideline, order set, and protocol prior to the work group convening to revise the document.

The purpose of the Review and Comment process is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the order set and protocol. Review and Comment also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes needed across systems in their organization to implement the guideline.

All member organizations are encouraged to provide feedback on order sets and protocol; however, responding to Review and Comment is not a criterion for continued membership within ICSI.

After the Review and Comment period, the work group reconvenes to review the comments and make changes as appropriate. The work group prepares a written response to all comments.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): For a description of what has changed since the previous version of this guidance, refer to Summary of Changes Report -- June 2008.

The recommendations for colorectal cancer (CRC) screening are presented in the form of an algorithm with a total of 14 components and accompanied by detailed annotations. An algorithm is provided for: Screening; clinical highlights and selected annotations (numbered to correspond with the algorithms) follow.

Class of evidence (A-D, M, R, X) ratings are defined at the end of the "Major Recommendations" field.

Clinical Highlights

Routine screening for colorectal cancer

- The patient meets the following criteria:
    - 50 years old, or if African American, 45 years old
    - No personal history of polyps and/or colorectal cancer
    - No personal history of inflammatory bowel disease
    - No family history of colorectal cancer in:
        - One first-degree relative diagnosed before age 60 **or**
        - Two first-degree relatives diagnosed at any age
    - No family history of adenomatous polyps in:
        - One first-degree relative diagnosed before age 60

(A single first-degree relative diagnosed with colorectal cancer after age 60 may put the patient at a slightly increased risk and may warrant starting colorectal cancer screening at age 40. A single first-degree relative with an adenomatous polyp diagnosed after age 60 may put the patient at a slightly increased risk and may also warrant starting colorectal cancer screening at age 40) *[C]*.

(*Annotation #3, Aim #1*)

- Colorectal cancer screening is recommended for all patients 50 years of age and older -- age 45 and older for African Americans -- using one of the following methods, based on joint decision-making by patient and provider:
    - Stool testing
        - Guaiac-based fecal occult blood testing (gFOBT) annually
        - Fecal immunochemical testing (FIT) annually
        - Stool deoxyribonucleic acid testing (sDNA) interval unknown
    - 60 cm flexible sigmoidoscopy every five years with or without stool test for occult blood annually
    - Double-contrast barium enema every five years
    - Computed tomography (CT) colonography every five years
    - Colonoscopy every 10 years

(*Annotation #5, 8, 9, 10, 11, 12; Aim #2*)

Screening Algorithm Annotations

1. **Prescreening Education and Counseling**

   This guideline represents the work group's contribution to colorectal cancer screening and must be seen within the larger context of all preventive health activities. The work group acknowledges the important role played by education and outreach efforts in helping to increase the number of risk-appropriate individuals who present themselves for colorectal cancer screening, thereby increasing the rate of early detection of this disease.

2. **Prevention Opportunity per Screening Method and Interval**

   Nearly every patient contact for any reason should be used as a possible prevention opportunity. Relying upon routine "checkup" appointments for the delivery of these services will clearly miss many patients, especially those who may need them the most. A prevention opportunity may be any visit to a provider that provides the opportunity for conducting the screening process, a preventive services visit and outreach to patients who historically do not come in for visits. It is important to consider ways to remind patients of their need for these services at other times than during office visits.

   Colorectal cancer screening is ranked as a Level I service in the ICSI Preventive Services for Adults guideline. A Level I service is a preventive service that providers and care systems must deliver (based on the best evidence).

3. **Meets Screening Criteria?**

   Since the term "screening" implies testing of asymptomatic individuals at average risk within the population, patients who are symptomatic or who have a history of gastrointestinal symptoms or disease may be excluded from this screening activity. Providers must make an individual decision on a case-by-case basis.

   The best data available support screening starting at age 50. No older age limit has been clearly established, although 80 has been suggested. The decision to stop screening would clearly be influenced by comorbidities, patient preferences and expected life span (at least 8 to 10 years to warrant continued screening).

   The patient must meet all four of the following criteria:

   - 50 years old, or if African American, 45 years old *[R]*
   - No personal history of polyps and/or colorectal cancer
   - No personal history of inflammatory bowel disease *[R]*
   - No family history of colorectal cancer in:
     - One first-degree relative diagnosed before age 60 **or**
     - Two first-degree relatives diagnosed at any age *[B]*

- No family history of adenomatous polyps in:
    - One first-degree relative diagnosed before age 60

A single first-order relative diagnosed with colorectal cancer after age 60 may put an individual at a slightly increased risk and may warrant starting colon cancer screening at age 40. A single first-degree relative with an adenomatous polyp diagnosed after age 60 may put the individual at a slightly increased risk and may also warrant starting colorectal cancer screening at age 40 *[C]*.

4. **Out of Guideline**

Patients who do not meet the screening criteria in Annotation #3, "Meets Screening Criteria?" may be at higher risk than average risk for colorectal cancer, and their management is not discussed in this guideline.

5. **Patient and Provider Choose Screening Test Pathway**

Screening intervals apply to patients between 50 years and older, or age 45 for African Americans, without clinical factors that place them at increased risk for colorectal cancer. Clinical groups may decide internally as to which screening pathway will be offered routinely at their site. Alternatively, individual clinicians may advise each patient as to which pathway might be most suitable and, with the patient's preference in mind, choose one of the pathways recommended in subsequent annotations.

When a provider suggests a specific screening pathway for colorectal cancer screening, the patient should be involved in the decision. The patient should be shown the choices and should receive information and/or advice on what the test can and cannot prove. The patient should also be informed as to what the follow-up on a positive test might involve.

Evidence from randomized controlled studies alone is insufficient to determine which screening test (flexible sigmoidoscopy or fecal occult blood test [FOBT]) produces greater benefit (or if both are more beneficial than either alone). However, the value of either in detecting colorectal cancer or adenomatous polyps has been proven. At this time, the choice of using one (or both) of these tests should be based on the judgment of the clinician including informed patient choice. In particular, attention is directed to the high rate of false-positive FOBTs and the failure of flexible sigmoidoscopy alone to screen the entire colon. As yet unproven is which screening test leads to the most efficient and effective use of colonoscopy.

Fecal occult blood tests, even when combined with flexible sigmoidoscopy, fail to detect colorectal cancer in at least 24% of those with cancer *[C]*.

The time interval for the development of malignant changes in adenomatous polyps is estimated at 5 to 25 years. Therefore, the work group has reached a conservative decision to recommend repeating the flexible sigmoidoscopy screening at five-year intervals. Some authors suggest that ten-year intervals

would be adequate. Some authors suggest that 10-year intervals would be adequate *[C]*.

If the provider and patient desire an examination of the whole colon, this can be accomplished by either colonoscopy, computed tomography (CT) colonography or in some situations, double-contrast barium enema. If the sigmoid colon is not well visualized on double-contrast barium enema, a flexible sigmoidoscopy should be obtained. The interval between examinations with colonoscopy is 10 years. The interval between examinations with CT colonography is five years. None of these strategies, however, are supported by direct evidence that they reduce mortality from colorectal cancer.

The recent American Cancer Society recommendations conclude that there is now sufficient data to include CT colonography as an acceptable option for colorectal cancer screening, and the recommended screening interval is every five years *[R]*.

Colonoscopy involves a higher risk of perforation than flexible sigmoidoscopy. If conscious sedation is used, there is risk of complications related to medication as well as a requirement for a period of post-procedure recovery and providing a driver for transport home after the procedure *[C]*.

8. **Stool Testing**

Guaiac-Based Fecal Occult Blood Testing (gFOBT) Annually

There are currently two commercially available methods for testing stool for occult blood: the guaiac-based tests (gFOBT) and immunochemical-based tests (FIT). Guaiac-based tests detect hemoglobin through the pseudoperoxidase activity of heme. Therefore, these tests are not specific for lower intestinal bleeding or even for human blood. The immunochemical-based tests react to human globin and therefore do not require the same dietary restrictions recommended for the guaiac-based fecal occult blood testing. Stool tests for occult blood are designed to detect cancers that may bleed periodically. The goal is to detect these cancers at an early stage that is amenable to therapy and thereby decrease mortality from colorectal cancer. Stool tests are not particularly effective in detecting precancerous polyps, particularly those under 1 cm to 2 cm in size.

There have been prospective randomized controlled trials demonstrating that guaiac-based tests reduce mortality from colorectal cancer by 15% to 33% *[A]*. The Minnesota Colon Cancer Control Study *[A]* also noted a 20% decline in the incidence of colorectal cancer after 18 years of follow-up, presumably because of the detection and removal of polyps in those undergoing colonoscopy for evaluation of a positive stool guaiac test.

There is considerable variability reported in the literature on the sensitivity and specificity of available guaiac-based stool tests. The reported sensitivity for detecting colorectal cancer with a single guaiac-based stool test ranges from 12.9% to 79.4% *[C]*. Tests with high sensitivity (such as Hemoccult SENSA) are preferred over lower sensitivity tests (such as Hemoccult II) to detect as many occult colorectal cancers as possible. Rehydration of guaiac-

based fecal occult blood testing is not recommended because of the increase in false-positives and the impact hydration has on the ability to accurately read the test. Testing stool obtained on rectal exam is not an acceptable form of colorectal cancer screening as this has the potential to miss over 90% of colorectal cancers *[C]*.

Patients using a high sensitivity guaiac-based fecal occult blood tests are generally instructed to avoid non-steroidal anti-inflammatory medications and more than one aspirin per day for seven days prior to testing. To avoid false-positive results from dietary factors the manufacturer of Hemoccult SENSA also recommends patients avoid red meat (beef, lamb and liver) for three days prior to testing and on the day of testing. In addition, vitamin C in excess of 250 mg per day should not be consumed for three days prior to testing or on the day of testing. Vitamin C can interfere with the pseudoperoxidase reaction, resulting in a false-negative test. Patients are instructed to collect two samples from three separate bowel movements for testing.

Advantages of guaiac-based fecal occult blood test are that it is readily available in most clinical settings and there is minimal risk to the patient when performing the test. Providers and patients need to be aware that studies demonstrating a reduction in colorectal cancer mortality with guaiac-based fecal occult blood testing followed a program of annual testing over an extended period of time with colonoscopic evaluation of all positive results. Patients choosing to do guaiac-based fecal occult blood test for colorectal cancer screening should do this annually and be willing to have a colonoscopy if any guaiac-based fecal occult blood testing is positive. Repeat stool testing after a positive guaiac-based fecal occult blood testing is not appropriate nor is follow up with a test other than colonoscopy.

Fecal Immunochemical Testing (FIT) Annually

Immunochemical stool tests to detect occult blood in stool use one or more monoclonal antibodies to human globin. These tests were developed to try to improve the specificity of stool testing for occult blood and to eliminate the need for dietary restrictions recommended for guaiac-based tests. Because human hemoglobin is digested in the stomach and small intestine, fecal immunochemical testing is more selective for colonic bleeding than are the guaiac-based tests.

The fecal immunochemical testing does not require dietary modification for patients and as with the guaiac-based test, is readily available in most clinical settings. These tests do not involve significant risk to the patient. However, just as with the guaiac-based tests, adherence to annual testing is necessary and patients with a positive test need to undergo colonoscopy.

This test employs immunochemical methods to test for blood in the stool. As it detects human globulin, this test is more specific and has low false-positive rates compared to the guaiac-based fecal occult blood test. For the same reason, the fecal immunochemical test does not yield false-negative results in the presence of high-dose vitamin C supplementation and is more specific for lower gastrointestinal bleeding *[C]*.

Stool Deoxyribonucleic Acid Testing (sDNA) Interval Unknown

Cells from the mucosal surface of the colon are shed into the lumen of the colon, and DNA alterations seen in colorectal cancer and in adenomas can be detected using a multitargeted DNA assay. Currently there is only one commercial stool DNA test for colorectal cancer in the U.S.: PreGen-Plus, available through Laboratory Corporation. This test is a second version of the original test; the majority of studies looking at the sensitivity and specificity of stool DNA were done with the first version of the test *[C]*. The sensitivity for detecting colorectal cancer in these studies was 52% to 91% and the specificity was 93% to 97%. There is currently a single study using the second version of the test that reports a sensitivity of 70% for detecting colorectal cancer *[C]*.

Patients choosing this option for colorectal cancer screening need to be aware that one complete bowel movement is collected and needs to be stored in the refrigerator or frozen until returned to the lab in a collection container supplied by the manufacturer. Stool sample sizes of less than 30 grams are not sufficient and the stool needs to reach the lab within 72 hours of the collection time. This test is currently not Food and Drug Administration (FDA) approved and reimbursement by insurers may be variable. The manufacturer recommends an interval of five years for stool DNA testing, but there is not a consensus regarding the testing interval. Any positive test needs to be evaluated with colonoscopy. It is currently unknown how to manage patients who have a positive stool DNA test but a negative colonoscopy *[R]*.

Neoplastic cells contained in layered DNA are continuously shed into the large bowel lumen. This test employs the detection of such cells in the stool with known DNA alterations leading to carcinogenesis. This test has statistically better sensitivity than the guaiac-based fecal occult blood test *[C]*. This test is not widely available, and there are still several unanswered questions related to its use: How frequently should the test be repeated after an initial negative one? What is the significance of a positive test, with a negative colonoscopy *[R]*?

9. **60 cm Flexible Sigmoidoscopy Every Five Years with or without Stool Test for Occult Blood Annually**

Flexible sigmoidoscopy can detect colorectal cancer and adenomatous polyps to the level of insertion of the scope. It is recommended that the scope be inserted to the splenic flexure or beyond 40 cm for the exam to be considered adequate *[R]*.

Patients who have adenomas of any size found at the time of sigmoidoscopy should undergo full colonoscopy because left-sided adenomatous polyps are associated with an increased risk of more proximal polyps or cancers *[C]*. Recent recommendations by the American Cancer Society state that endoscopists performing flexible sigmoidoscopy should be skilled in obtaining biopsies of polyps, or if biopsies are not obtained, all patients with polyps greater than 5 mm should be further evaluated with full colonoscopy *[R]*. The consensus of this work group was that all patients with polyps not completely removed at the time of sigmoidoscopy should undergo colonoscopy.

The accuracy of flexible sigmoidoscopy, as well as colonoscopy, is dependent on the training and skill of the endoscopist as well as the quality of the bowel preparation. It is recommended that providers exceed the minimum number of training exams delineated in the American Society for Gastrointestinal Endoscopy guidelines before conducting flexible sigmoidoscopies without supervision *[R]*. Studies comparing flexible sigmoidoscopy to colonoscopy have found that the shorter exam is 60% to 70% sensitive for colorectal cancer and advanced adenomas, as compared to the complete exam. Providers and patients should be aware that some patient populations have a higher prevalence of right-sided lesions. Significant lesions are more common in the proximal or right colon after the age of 65 *[D]*. Women are more likely to have proximal or right-sided adenomas or colorectal cancer than are men *[B]*. Ethnicity may also affect the distribution of lesions in the colon. African Americans may have more proximal lesions as compared to Whites *[C]*. Whites may have more proximal lesions when compared with Hispanics and Asians *[D]*, *[C]*. Those groups at higher risk of proximal lesions may benefit from visualization of the entire colon with colonoscopy or CT colonography rather than flexible sigmoidoscopy.

Flexible sigmoidoscopy can be preformed alone as a screening test every five years or combined with annual stool occult blood testing, either guaiac-based fecal occult blood testing or fecal immunochemical testing. If the combination of the two tests is chosen by the patient and their provider, it is preferable to do the stool occult blood testing first. If a positive stool test is detected, the patient should go directly to colonoscopy, thereby avoiding an unnecessary sigmoidoscopy.

Patients should be aware of the limitations of flexible sigmoidoscopy. Only the left side of the colon will be seen with flexible sigmoidoscopy. In most clinical practices, flexible sigmoidoscopy is performed as an office procedure without sedation. This can be associated with some discomfort during and after the exam *[B]*. However, some patients may prefer an exam without sedation so that they can drive or return to work after the procedure. Flexible sigmoidoscopy does require the use of a bowel prep. The risk of colonic perforation with sigmoidoscopy without biopsy or polypectomy is less than 1 in 20,000 *[A]*, *[B]*. Lesions can be missed on sigmoidoscopy, and advanced neoplasia has been found within three years of an exam in published studies *[R]*. Patients should understand that finding polyps on a flexible sigmoidoscopy will result in the need for colonoscopy.

10. **Double-Contrast Barium Enema Every Five Years**

A double-contrast barium enema (DCBE) or a fluoroscopic barium enema by a radiologist with specialized training in gastrointestinal procedures may be performed. The fluoroscopic barium enema should be performed in conjunction with proctoscopy or flexible sigmoidoscopy *[C]*.

There are no studies evaluating whether screening by barium enema alone reduces mortality from colorectal cancer in people at average risk for the disease. This option is based on evidence that screening double-contrast barium enema and fluoroscopic barium enema by a gastrointestinal

radiologist can image the entire colon and detect cancers and large polyps almost as well as colonoscopy or flexible sigmoidoscopy.

The screening method of double-contrast barium enema does have some limitations. In one study, it was found to be less accurate than well-performed CT colonography *[C]*. Many radiologists have found that decreasing frequency of performance of this examination means that radiologist performance skills and training of new radiologists to perform this test are decreasing, and the quality of this examination is more dependent on a high-quality bowel preparation than the quality of CT colonography and colonoscopy are dependent on a high-quality bowel preparation.

11. **CT Colonography Every Five Years**

CT colonography (virtual colonoscopy) has been developed to provide a minimally invasive total colon evaluation with accuracy similar to colonoscopy. It is currently recommended as a test that detects adenomatous polyps and cancer by the joint guideline from the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology *[R]*. It allows evaluation of the entire colon. Currently, however, CT colonography is being performed and reimbursed as a colorectal cancer screening procedure at only a few sites.

The other nationally approved radiographic method of total colon evaluation, double-contrast barium enema, has been shown to be inferior to CT colonography for polyp detection in over 800 asymptomatic persons at greater than average risk for colorectal cancer *[C]*. A recent meta-analysis confirmed that the sensitivity and specificity of the CT colonography for polyps greater than or equal to 6 mm are greater than the sensitivity and specificity of double-contrast barium enema for these polyps *[C]*.

However, the more important question is the performance of CT colonography in a screening population in comparison to colonoscopy. The most impressive screening CT colonography performance for polyp detection in an asymptomatic population was documented in a study, performed on over 1,200 asymptomatic adults with an average risk of colon cancer *[C]*. This study demonstrated a CT colonography sensitivity of 94% for polyps measuring at least 1 cm.

How rapidly CT colonography becomes a common screening test for colorectal cancer will depend on reimbursement for the test, training of radiologists and a nationwide effort by the American College of Radiology to monitor and improve CT colonography quality.

Additionally, CT colonography is the best total colonic imaging examination in the following clinical situations: after incomplete screening or diagnostic colonoscopy; for anticoagulated patients who cannot safely discontinue anticoagulation therapy; and for patients who refuse endoscopy. In many locations, CT colonography is not available, and barium enema can be performed in the situations described above.

The limitations with CT colonography include the fact that the radiologists must be qualified to perform and interpret CT colonography by undergoing training and demonstrating competence prior to performing and interpreting this test *[C]*; another limitation is that patients will need to undergo colonoscopy if the CT colonography demonstrates a colonic polyp 1 cm or larger and possible for a colonic polyp 0.6 cm or larger (depending on physician and patient preference).

12. **Colonoscopy Every 10 Years**

Colonoscopy allows evaluation of the entire colon and has the advantage of being both a diagnostic and therapeutic procedure. Biopsies can be obtained and polypectomies can be performed to remove precancerous and early-stage cancerous lesions. There have not been any prospective randomized controlled trials of screening colonoscopy. However, there is significant evidence that detection and removal of adenomatous polyps leads to a reduction in the incidence of colorectal cancer. The National Polyp Study reported a reduction in colorectal cancer incidence of 76% to 90% after clearing colonoscopy *[B]*. The reductions in colorectal cancer incidence reported in studies of fecal occult blood testing and flexible sigmoidoscopy are attributed to the fact that those individuals with positive screening tests then went on to colonoscopy and removal of precursor lesions. National consensus guidelines suggest an interval of 10 years between colonoscopies after a negative exam for the average-risk population *[R]*.

One study concluded that colonoscopy is indicated for individuals 40 years of age and older who have a first-degree relative with colon cancer *[D]*.

13. **Positive Findings?**

A positive guaiac-based fecal occult blood test, fecal immunochemical test or stool DNA test all require further evaluation with colonoscopy. Use of another screening modality such as repeating a stool test, barium enema, flexible sigmoidoscopy or CT colonography is not appropriate. The management of the patient with a positive stool DNA test but a negative colonoscopy is unknown at this time and will need to be individualized for each patient.

A positive finding on flexible sigmoidoscopy would be an adenomatous polyp of any size and would warrant further evaluation with colonoscopy *[C]*. From the standpoint of colorectal cancer screening, diverticula and small left-sided hyperplastic polyps are not precursors to cancer and do not need further evaluation. Large hyperplastic polyps proximal to the splenic flexure may be precursors to cancer and additional follow-up may be warranted *[D]*, *[R]*. There are currently no published or society-endorsed guidelines regarding follow-up of concerning hyperplastic polyps. Characteristics of hyperplastic polyps that should raise concern are multiple hyperplastic polyps proximal to the sigmoid colon, large size (greater than 10 mm – as a frame of reference, most biopsy forceps open to a width of 7 mm), a family history of hyperplastic polyposis syndrome or a family history of colorectal cancer. Follow-up of these patients at this time is individualized but should be at least as aggressive as follow-up for patients with adenomatous polyps *[R]*.

Current American Cancer Society recommendations are that any polyp of 6 mm or greater size seen on double-contrast barium enema should be evaluated with colonoscopy *[R]*.

Patients found to have a polyp of 10 mm or larger on CT colonography should be referred for colonoscopy. Patients with three or more polyps of 6 mm or greater should also be referred for colonoscopy. The American Cancer Society guidelines recommend colonoscopy for any patient with a polyp of 6 mm or greater size *[R]*.

If a patient has one or more polyps greater than or equal to 6 mm demonstrated by double-contrast barium enema or CT colonography, colonoscopy will be recommended. Clinicians should be aware that radiologists do not usually report polyps less than or equal to 5 mm by CT colonography, although there is no multidisciplinary consensus regarding the reporting and management of these small polyps. Clinicians should also be aware that CT colonography provides technically limited images of the entire abdomen and pelvis; therefore, a positive finding outside of the colon (extracolonic) may require additional evaluation even though the colon test is negative.

Definitions:

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm is provided for: Screening.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Decreased mortality from colorectal cancer due to earlier detection

POTENTIAL HARMS

- *Colonoscopy*. Colonoscopy involves a higher risk of perforation than flexible sigmoidoscopy. If conscious sedation is used, there is a risk of complications related to medication as well as a requirement for a period of post-procedure recovery and providing a driver for transport home after the procedure.
- *False positive screening tests*. There is a high rate of false-positive fecal occult blood tests. The fecal immunochemical testing is more specific and has low false-positive rates compared to the guaiac-based fecal occult blood test.
- *False negative screening tests*. Fecal occult blood tests (FOBTs), even when combined with flexible sigmoidoscopy, fail to detect colorectal cancer in at least 24% of those with cancer.
- *Sigmoidoscopy*. The risk of colonic perforation with *sigmoidoscopy* without biopsy or polypectomy is less than 1 in 20,000. Lesions can be missed on sigmoidoscopy, and advanced neoplasia has been found within three years of an exam in published studies.

QUALIFYING STATEMENTS

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- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This medical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.
- Evidence from randomized controlled studies alone is insufficient to determine which screening test (flexible sigmoidoscopy or fecal occult blood test) produces greater benefit (or if both are more beneficial than either alone). However, the value of either in detecting colorectal cancer or adenomatous polyps has been proven. At this time, the choice of using one (or both) of these tests should be made on the judgment of the clinician including informed patient choice. In particular, attention is directed to the high rate of false-positive fecal occult blood tests and the failure of flexible sigmoidoscopy alone to screen the entire colon. As yet unproven is which screening test leads to the most efficient and effective use of colonoscopy.
- There are no studies evaluating whether screening by barium enema alone reduces mortality from colorectal cancer in people at average risk for the disease. This option is based on evidence that screening double contrast barium enema and fluoroscopic barium enema by a gastrointestinal radiologist can image the entire colon and detect cancers and large polyps almost as well as colonoscopy or flexible sigmoidoscopy.
- Neither colonoscopy, computed tomography (CT) colonography, nor double-contrast barium enema are supported by direct evidence that they reduce mortality from colorectal cancer.
- There have not been any randomized controlled trials of the effects of fecal immunochemical testing on mortality from colorectal cancer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Establish processes for both identifying age-appropriate individuals who have not undergone appropriate screening and contacting these patients to encourage them to do so (examples may include chart reminders, computer-generated reminder letters, etc.)

IMPLEMENTATION TOOLS

Clinical Algorithm
Pocket Guide/Reference Cards
Quality Measures

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NQMC MEASURES

- Colorectal cancer screening: percentage of patients age 50 and older who are up-to-date with colorectal cancer screening.
- Colorectal cancer screening: percentage of African American patients age 45 and older who are up-to-date with colorectal cancer screening.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Colorectal cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Jun. 27 p. [57 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1995 May (revised 2008 Jun)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

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GUIDELINE COMMITTEE

Preventive Services Steering Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: John Mageli, MD (Work Group Leader) (Aspen Medical Group) (Internal Medicine); Scott Boyers, MD (Sanford Health) (Family Medicine); Christopher Carlson, MD (Camden Physicians) (Family Medicine); Jerome Potts, MD (Hennepin County Medical Center) (Family Medicine); Irshad Jafri, MD (HealthPartners Medical Group) (Gastroenterology); Theresa Smith, MD (St. Mary's/Duluth Clinic Health Systems) (Gastroenterology); Joseph Tombers, MD (Minnesota Gastroenterology) (Gastroenterology); John Barlow, MD (Mayo Clinic) (Radiology); Penny Fredrickson (Institute for Clinical Systems Improvement) (Measurement Advisor/Implementation Advisor); Melissa Marshall, MBA (Institute for Clinical Systems Improvement) (Facilitator)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

ICSI has adopted a policy of transparency, disclosing potential conflict and competing interests of all individuals who participate in the development, revision and approval of ICSI documents (guidelines, order sets and protocols). This applies to all work groups (guidelines, order sets and protocols) and committees (Committee on Evidence-Based Practice, Cardiovascular Steering Committee, Women's Health Steering Committee, Preventive & Health Maintenance Steering Committee, Respiratory Steering Committee and the Patient Safety & Reliability Steering Committee).

Participants must disclose any potential conflict and competing interests they or their dependents (spouse, dependent children, or others claimed as dependents) may have with any organization with commercial, proprietary, or political interests relevant to the topics covered by ICSI documents. Such disclosures will be shared with all individuals who prepare, review and approve ICSI documents.

John Barlow received a honorarium/consulting fee from MedicTrainer (London, England).

No other work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's Web site at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Colorectal cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Jun. 50 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Colorectal cancer screening. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2008 Jun. 1 p. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.
- ICSI pocket guidelines. May 2007 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2007.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

None available

NGC STATUS

This summary was updated by ECRI on April 30, 1999. The information was verified by the guideline developer as of July 6, 1999. This summary was updated by ECRI on May 15, 2000, December 20, 2001, and December 24, 2002. The updated information was verified by the guideline developer on January 23, 2003. The summary was updated by ECRI on March 31, 2004, October 8, 2004, July 29, 2005, and most recently on July 11, 2006. This summary was updated by ECRI Institute on August 14, 2008.

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